REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 1, 5 and 10-12 will be active in the application subsequent to entry of this Amendment.

As a preliminary matter, please note the Information Disclosure Statement filed February 27, 2008 after the mailing date of the current Official Action.

Action was taken within the allotted three months' time for submitting this information and the appropriate statement has been made, thus no fee is involved. The examiner is requested to take into account this article during further review of this application.

Amendments to the Claims

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention and direct them to elected, examined subject matter. The subject matter of claim 4, that is within four hours of on-set of symptoms, has been incorporated into claim 1.

Claims 2, 6-9 and 12-17, all directed to non-elected subject matter and currently withdrawn from consideration, have been canceled, this action being taken without disclaimer or prejudice to continuing application(s) directed to this subject matter.

Response to Obviousness-Type Double Patenting

Previous claims 1, 3-5, 10 and 11 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 8-11 and 14 of co-pending application Serial No. 11/629,202. Although this is a provisional rejection applicant wishes to resolve and dispose of the issue, hence submitted herewith is a Terminal Disclaimer over Serial No. 11/629,202.

The sole issue remaining in the current Official Action is a prior art-based rejection. Before discussing this applicant wishes to further explain and highlight the contributions to the art as provided by the present invention as explained in his specification.

Applicant's Contribution to the Art

At the time the present application was filed myocardial infarction was (and still remains) one of the most common cause of deaths in the developed countries.

Claim 1 as now amended relates to the use of L-carnitine for the treatment of myocardial infarction, in which L-carnitine is administered *intravenously* within the first four hours of onset

of the symptoms of acute myocardial infarction at an initial dose of 9 grams a day for 5 days, after which the treatment is continued as an *oral* dose of 4 grams a day.

Before the filing date of the present application the use of L-carnitine for treating myocardial infarction was already known in the art. The present invention is an improvement related to the specific procedures for the use of L-carnitine for treating myocardial infarction. The present invention is directed to reducing the number of deaths in patients affected by myocardial infarction.

At the time the present application was filed it was not known that patients affected by myocardial infarction, when treated within the first 4 hours from chest pain with L-carnitine, in particular at the dosages and using the particular administration regimen would have increased their survival rate.

This is the teaching of the present invention.

As above mentioned the present invention permits a significant reduction of the number of deaths in patients affected by myocardial infarction with respect to the available treatments.

Response to Rejection under 35 USC § 103(a)

Claims 1, 3-5, 10 and 11 have been considered obvious in the light of D1 (Journal of the American College of Cardiology) alone or in combination with D2 (US2002/0002202). To the extend these documents are thought to pertain to the claims now presented for examionatoin this rejection is traversed.

Document D1 corresponds to the clinical trial called "CEDIM". This clinical trial CEDIM is already identified and discussed on page 4 lines 13-21 of the application as filed.

The improved method of treatment according to the present invention to be efficient requires that three conditions are satisfied:

- *First condition*: a particular dose of L-carnitine has to be administered (*9 grams a day* for 5 days intravenously, after which the treatment is continued as a dose of *4 grams a day* by mouth).

- *Second condition*: a particular protocol of L-carnitine administration has to be used (9 grams a day *for 5 days intravenously, after which the treatment is continued* as a dose of 4 grams a day *by mouth*).

-*Third condition*: the treatment must be started within the first *4 hours from the onset of chest pain.*

Document D1 does not satisfy the *third condition*; in fact, the treatment is started only after 5.5 hours from chest pain (12.7±7.17 h) see page 382, RESULTS, first column, line 3 of D1. For this reason in the CEDIM trial (D1) the number of deaths at hospital in the "intense care unit" were *11* in the treated group *vs 14* in the control group (see page 385 Table 5 of D1), and this difference is not statistically significant.

According to the present invention the number of deaths at hospital in the "intense care unit" (for example after 5 days) was *27* in the treated group *vs 43* in the control group (*see* page 14 Table 1) and this difference is statistically significant.

Moreover, on page 8 first and second paragraph of the present application as filed it is reported: *"A given number of patients ...with acute myocardial infarction continue to die in the first week of hospitalization .... Furthermore, L-carnitine alone in the therapeutic regimens adopted to date ... fails to reduce the number of deaths as compared to patients treated with the normal drugs used.*

There is therefore a strongly perceived need for... reducing the number of deaths due to acute myocardial infarction ... within the first week ... after the onset of infarction" (Emphasis added.)

Since in the medical field it is important to save even a single human life, if it was so obvious to adopt a different administration regimen, doctors would have already used the study design of the present invention to reduce the number of deaths. If it is not trivial to save even a single human life (with respect to the available treatments) than the present invention should not be considered obvious in the light of D1. For this reason D1 alone should be considered irrelevant.

Document D2 (US2002/0002202) adds nothing to the contents of D1 as it relates to the use of L-carnitine acid fumarate to prepare a composition suitable for reducing the risk of onset of organ ischemia and particularly on the ischemic heart.

On page 3 left column of D2 is reported an experimental model for ischemia recognized as valid for cardiac ischemia.

In contrast, the present invention relates to the use of L-carnitine for reducing the number of deaths in patients affected by myocardial infarction with respect to the available treatments.

Again, the improved method of treatment according to the present invention to be efficient requires that three conditions are satisfied:

- *First condition*: a particular dose of L-carnitine has to be administered (*9 grams a day* for 5 days intravenously, after which the treatment is continued as a dose of *4 grams a day* by mouth).

- *Second condition*: a particular protocol of administration L-carnitine has to be used (9 grams a day *for 5 days intravenously, after which the treatment is continued* as a dose of 4 grams a day *by mouth*).

-*Third condition*: the treatment must be started before *4 hours from chest pain.*

Document D2 does not satisfy any of the three conditions mentioned above.

The combination of D1 with D2 is illogical and in any event if made still does not suggest the subject matter defined by applicant's claims as presented above.

For the above reasons it is respectfully submitted that the combination of documents relied upon in the Official Action still does not render the claims of this application, particularly as above amended, unpatentable. Reconsideration and allowance are solicited.

Respectfully submitted,

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